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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,502	03/17/2006	Nitin Bhalachandra Dharmadhikari	2867.003US1	4377

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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07/26/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No. 10/572,502	Applicant(s) DHARMADHIKARI ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-40 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-40 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 3/19/10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites that the 'active ingredient present in the one or more layers is different', however if the drug delivery system comprises one layer, what is the active ingredient different from? It is unclear what exactly is being claimed, whether the active ingredient is different from the other components of the core (an inherent feature) or if other, separate layers are required that differ in some way from one another. If the latter is the case, the term "different" would be relative as there is no definition of limit to differences in composition down to the molecular level, i.e. multiple levels could have HPMC and naproxen, where one layer have HPMC of a higher molecular weight than the other, or of a different granular size, etc. Clarification of this claim is required.

For the purposes of Examination the claim will be interpreted as a drug delivery system where the active ingredient and swellable composition is present in one layer.

Claim 42 recites an orally administrable drug delivery system in the form of a multilayered tablet, yet only recites one layer. The core comprises at least one layer comprising an active ingredient composition and a swellable or reactive composition. No other layers are

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recited. As such the claim reads on any monolithic tablet with a coating surrounding it, and not on a multilayered tablet.

For the purposes of the invention the claim will be interpreted as a single layer tablet with a coating surrounding it.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-32, 34-38 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashida et al (USPN 5,593,694 hereafter '694).

The '694 patent teaches an oral administrable drug delivery system comprising a core and a coating (abstract). The core comprises an active ingredient along with an excipient (col. 5, lin. 60-col. 6, lin. 65). The core tablet further comprises swellable portions (col. 4, lin. 34-60). The core is surrounded by a coating that is in immediate vicinity of the drug and swellable portions. The periphery of the coated tablet is thinner than the top and bottom and upon administration will absorb water (col. 4, lin. 12-34). The coating is semipermeable to water around the edges (col. 7, lin. 10-20). The water absorption activates the water swellable portions of the core tablet forcing release of the active agent, while the top and bottom portions of the coating remain intact (Figures 2A, 2B). The sides of the coating are preselected to be removed after contact with the aqueous environment of the body, while the top and bottom portions are not removed (*Ibid.*)

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Since the tops and bottom of the dosage form does not dissolve or transmit drug to the aqueous environment, the side act as passageways for the drug to move through. The swellable agents include cellulose wicking agents, and osmogents such as lactose (col. 5, lin. 60-65). The dosage form is capable of zero-order release of the active agents (col. 7, lin. 30-35). The solid core tablet is a compressed tablet comprising a single layer of the components comprising both the active ingredient components and the swellable composition (Examples). These disclosures render the claims anticipated.

Claims 25, 26, 28, 30-40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte et al (USPN 6,294,200 hereafter '200).

The '200 patent teaches a coated tablet comprising a core and a coating (abstract). The core comprises layers (Figures), comprises an active pharmaceutical component comprising excipients (col. 4, lin. 55-65; col. 7, lin. 53-col. 8, lin. 26) and a swelling components (col. 5, lin. 29-40). The swellable components comprise swellable components like cellulose wicking agents, osmogents like lactose, (col. 5, lin. 10-25). The formulation comprises a second active ingredient that is release in an immediate release form (part 5, col. 3, lin. 60-65). The coating surrounds the core layers with the swellable layer in contact with the coating (part 2, Figure 3). The swellable components are present as an in-lay tablet layer surrounding by the coating (Figures). Upon release the immediate release portion is removed and exposes the core layers. The coating polymer is impermeable to the drug composition comprising cellulose phthalates (col. 6, lin. 25-45). The formulation is further coated with pH dependent coating (col. 7, lin. 10-20). These disclosures render the claims anticipated.

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Response to Arguments

Applicant's arguments with respect to claims 25-40 and 42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618